DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

December 21, 2006

Via FEDEX

Re: MQSA Inspection ID # 1901570012
FEI# 1000523487

Dale A. Kirby, Chief Executive Officer
Colusa Regional Medical Center
199 E. Webster Street
Colusa, CA 95932

Dear Mr. Kirby:

On July 7, 2006, a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector mailed to your facility on July 24, 2006. The violations are again identified below.

Level 1: Phantom QC records were missing for at least four (4) weeks for unit [redacted], room Mammo (21 CFR 900.12(e)(2)(iii)). Specifically, phantom control charts had missing scores for the evaluation of fibers, specks and masses for July 5, 2005 through December 13, 2005. In addition, the associated phantom QC films were not available for review.

Level 2: Processor QC records in the month of January 2006 were missing for at least 10% but less than 30% of the operating days, for processor [redacted] room Mammo, at site Colusa Regional Medical Center (21 CFR 900.12(e)(1)). Specifically, processor QC records were not available for January 16, 23, and 30, 2006. In addition, our review found QC

films and charts for days that do not exist, for example, February 29, 30 & 31, 2006.

Level 2: Failed to produce documents verifying that the interpreting physician, [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms within 24 months (21 CFR 900.12(a)(1)(ii)(A)).

We received your response, dated July 29, 2006, to the MQSA Facility Inspection Report. Your response was inadequate in that you failed to identify the root cause of the quality problems and therefore you cannot assure that your corrective actions adequately address the violations.

On August 24 and 25, 2006, a representative of the Food and Drug Administration (FDA) performed a MQSA follow-up inspection of your facility. This MQSA follow-up inspection revealed that your facility failed to correct the violations identified below.

Level 1: Phantom QC records were missing for at least four (4) weeks for unit [redacted], room Mammo (21 CFR 900.12(e)(2)(iii)).

Level 2: Processor QC records in the month of January 2006 were missing for at least 10% but less than 30% of the operating days, for processor [redacted], room Mammography, at site Colusa Regional Medical Center (21 CFR 900.12(e)(1)).

In addition, the follow-up inspection found the following violations:

Level 2: Corrective actions for processor QC failures were not documented at least once for processor [redacted], room Mammo at site Colusa Medical Center (21 CFR 900.12(e)(8)(ii)(A)).

Level 2: Corrective action before further exams, for a failing phantom image score (missing charts and films) was not documented for unit [redacted] room Mammo (21 CFR 900.12(e)(8)(ii)(A)).

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- requiring your facility to notify patients who received mammograms at your facility, and their referring physicians, of the deficiencies, the

potential harm resulting from such deficiencies, appropriate remedial measures, and other relevant information

- seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. sample records that demonstrate proper record keeping procedures;

Please submit your response to this letter to:

Russell A. Campbell, Compliance Officer
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 84501

Please send a copy of your response to:

Edward W. Gloor, Chief
Inspection Compliance and Enforcement
Department of Health Services
Radiological Health Branch
P.O. Box 997414 MS 7610
Sacramento, CA 95899-7414

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection(s) of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program,

Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell at 510-337-6861.

Sincerely yours,

Barbara Cassens
District Director

cc:

Edward W. Gloor, Chief
Inspection Compliance and Enforcement
Department of Health Services
Radiological Health Branch
P.O. Box 997414 MS 7610
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